IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **ALL WAVE 3 TVT AND** **TVT-O CASES IDENTIFIED IN** **PLAINTIFFS' EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE DR. LARRY T. SIRLS' TVT/TVT-O GENERAL OPINIONS

Defendants Ethicon, Inc., Ethicon LLC, and Johnson & Johnson (collectively, "Ethicon"), incorporating the standard of review set out in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D. W. Va. 2014),[1] submit this opposition to Plaintiffs' Notice of Adoption of Prior *Daubert* Motion of Larry T. Sirls, II, M.D., for Wave 3 [Doc. 2804], which incorporates Plaintiffs' Motion to Exclude the General Opinion Testimony of Dr. Larry T. Sirls [Doc. 2479] and accompanying memorandum [Doc. 2480] ("Pls.' Memo.").

INTRODUCTION

Plaintiffs fail to state legitimate grounds for exclusion of Dr. Larry Sirls' opinions about Ethicon's TVT or TVT-Obturator (TVT-O) devices. For the most part, they seek blanket exclusion of his testimony without specifying which of Dr. Sirls' opinions are supposedly unreliable. As the Court has held multiple times previously, it cannot be reasonably asked to evaluate admissibility based on Plaintiffs' vague criticisms and should deny Plaintiffs' motion on

[1] *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

this basis.[2] To the extent these criticisms have any viability, they are matters for cross-examination, not exclusion under *Daubert*. The Court should deny Plaintiffs' motion in its entirety.

ARGUMENT AND AUTHORITIES

Because Plaintiffs challenge Dr. Sirls' qualifications with respect to certain proffered opinions, Ethicon provides the following overview of Dr. Sirls' background and experience to illustrate why Plaintiffs' challenges to the reliability of his opinions lack merit. Dr. Sirls is a graduate of the University of Michigan Medical School and received his post-graduate training in urology and female urology, neurourology, and urodynamics at the Henry Ford Hospital and the Kaiser Permanente Medical Center respectively. Ex. A, Sirls General Rep. at 1. Dr. Sirls currently serves as a Professor at the Oakland University William Beaumont School of Medicine and is the Director of the Female Pelvic Medicine and Reconstructive Surgery fellowship program, one of few urology-directed programs in the country. *Id.* at 2. He has been an academic teaching faculty member since 1993. *Id.* at 1. Dr. Sirls is a member of numerous relevant medical associations, including the American Urologic Association and the American Association of Clinical Urologists, and is a Fellow with the American College of Surgeons. Ex.

[2] "[W]ithout identifying the specific expert testimony to be excluded, the parties ask the court to prevent experts from offering testimony the expert is not qualified to offer. I will not make speculative or advisory rulings. I decline to exclude testimony where the party seeking exclusion does not provide specific content or context." *See, e.g.*, *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-2327, 2016 WL 4582232, at *5 (S.D. W. Va. Sept. 1, 2016) (*Daubert* decision regarding Dr. Dionysios K. Veronikis); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-2327, 2016 WL 4556807, at *6 (S.D. W. Va. Aug. 31, 2016) (*Daubert* decision regarding Brian J. Flynn, M.D.); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-2327, 2016 WL 4536885, at *5 (S.D. W. Va. Aug. 30, 2016) (*Daubert* decision regarding Michael Thomas Margolis, M.D.); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2:12-md-2327, 2016 WL 4493685, at *5 (S.D. W. Va. Aug. 25, 2016) (*Daubert* decision regarding Peggy Pence, Ph.D.).

B, Sirls Curriculum Vitae at 3. Dr. Sirls is also certified by both the American Board of Urology and the American Urologic Association, and has been for over twenty years. *Id.*

Dr. Sirls has extensive training and experience in a variety of treatments for urinary incontinence and pelvic prolapse, including "native tissue repair of urinary incontinence, fascial pubovaginal sling, vaginal approach needle suspensions[,] and the Burch bladder neck suspension." Ex. A, Sirls General Rep. at 1. He has implanted thousands of mesh slings and other mesh products in his twenty-five years of clinical experience. *Id.* at 29, 84. He started by, and has more than ten years of experience in, performing fascial pubovaginal slings and Burch suspensions. *Id.* at 84. He has since acquired more than ten years of experience implanting both retropubic and transobturator slings such as the TVT and TVT-O. *Id.*

Since 2007, Dr. Sirls' extensive experience has led him to becoming the primary investigator at William Beaumont Hospital for the Urinary Incontinence Treatment Network, where he has participated in numerous trials sponsored by the National Institutes of Health evaluating the surgical treatment of urinary incontinence. *Id.* at 1–2. In particular, Dr. Sirls was involved in NIH-funded studies comparing the fascial pubovaginal slings and the Burch bladder suspension, a trial comparing retropubic and transobturator slings, and a trial analyzing preoperative urodynamics in women undergoing surgical treatment for stress urinary incontinence (SUI). *Id.* at 2; *see also* Ex. B, Sirls Curriculum Vitae at 23–25. Further demonstrating Dr. Sirls' expertise is his lengthy list of publications and presentations on the topic of female pelvic medicine. Ex. B, Sirls Curriculum Vitae at 3–21. Moreover, Dr. Sirls' expertise is recognized by others in this field as he serves as a peer-reviewer on the Journal of Urology. Ex. C, Sirls 7/21/16 Dep. Tr. at 28:16–22.

Dr. Sirls also demonstrated his familiarity with and reliance on the medical literature regarding the TVT and TVT-O devices for his clinical practice. For example, he testified that he was "cautious" and "watched the literature" before adopting the use of the TVT and TVT-O in his practice. *Id.* at 45:8–47:6. In fact, Dr. Sirls continuously participates in a "journal club" every month to review new literature in his field with his colleagues in order to be aware of the most recent research. *Id.* at 133:8–14.

A surgeon with Dr. Sirls' experience is allowed to examine the literature and offer opinions regarding the safety and efficacy of the TVT and TVT-O. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D. W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit").

Nonetheless, Plaintiffs purport to identify ways in which Dr. Sirls' opinions are allegedly inadequate. Pls.' Memo. at 4–7. Their challenges fail to state legitimate grounds for exclusion.

I. Plaintiffs' Cursory Challenge to Dr. Sirls' Opinions on the Safety and Efficacy of the TVT and TVT-O Devices is Fatally Vague as Well as Unsupported. (Pls.' Memo. Section A)

A. Plaintiffs' Objection Based on Dr. Sirls' Experience with the TVT-Abbrevo Fails to State a Legitimate *Daubert* Objection.

Pointing to testimony in which Dr. Sirls responded to Plaintiffs' counsel's questions about when and why he uses the TVT-Abbrevo versus when he uses other products, Plaintiffs declare that Dr. Sirls "grounded many of his opinions regarding the TVT-O in his clinical experience with Ethicon's Abbrevo device" and argue that "to the extent" he has done so, "such opinions must be excluded." Pls.' Memo. at 4 (citing Ex. C, Sirls 7/21/16 Dep. Tr. at 55:8–64:1). The testimony they cite, however, does not remotely support their argument, and—tellingly—Plaintiffs fail to identify any specific opinions they challenge on this basis.

Ethicon cannot reasonably be expected to answer, nor the Court to evaluate, such a vague challenge. *See, e.g.*, discussion *supra* note 2; *see also Server Tech., Inc. v. Am. Power Conversion Corp.*, No. 3:06-CV-00698-LRH, 2014 WL 1308617, at *5–6 (D. Nev. March 31, 2014) (denying APC's motion *in limine* in part because APC failed to identify or specify the evidence or testimony it sought to exclude); *Ratay v. Montgomery Ward and Co.*, No. 92-C-3965, 1993 WL 189864, at *1 (N.D. Ill. June 2, 1993) (denying the plaintiff's motion *in limine* regarding post-termination evidence because plaintiff had failed to identify specific witnesses whose testimony she sought to exclude). If Plaintiffs believe Dr. Sirls' current use of the TVT-Abbrevo device undercuts his opinion about the safety of the TVT or TVT-O devices, as their argument implies, they are free to cross-examine him on the subject. *See, e.g.*, Pls.' Memo. at 4 ("Dr. Sirls testified that he preferred the shorter length of mesh in the Abbrevo, precisely because of its potential to reduce some complications[.]"). That belief, however, is not grounds for a *Daubert* challenge.

Furthermore, Dr. Sirls is fully entitled, consistent with reliable scientific principles, to base his opinions about the TVT and TVT-O in part on his experience with similar products, including the TVT-Abbrevo. Plaintiffs make much of the fact that Dr. Sirls apparently

recognizes some of the differences between Ethicon's TVT-O and TVT-Abbrevo devices. Pls.' Memo. at 4. But Dr. Sirls also testified about numerous similarities between the two obturator and the two retropubic devices:

> Q: But apart from the cutting technique, [the TVT-Abbrevo] uses the same mesh [as the TVT-O]?
>
> A: Yes, it's the same mesh.
>
> Q: And there's laser-cut TVT-O mesh, correct?
>
> A: There is, that's correct.
>
> Q: In addition to mechanically cut TVT-O devices?
>
> A: That's correct.
>
> Q: But the mesh in the TVT-Abbrevo and the TVT-O is the same polypropylene?
>
> A: Yes, it's the same weave, monofilament.
>
> Q: It's the same weight or density?
>
> A: Same weight, same pore size. It's a hundred grams per liter squared.
>
> Q: Does the mesh used in the two devices lay under the urethra at the same spot?
>
> A: It does. We do that on purpose.
>
> Q: Does the TVT-Exact use the exact same mesh as the TVT with the exception of the cutting technique?
>
> A: Yes, yes, it is.
>
> Q: But, again, with the TVT there's also laser-cut mesh available, is that your understanding?
>
> A: That's correct.
>
> Q: And is the TVT-Exact mesh the same weight and pore size as the TVT mechanically cut mesh?

A: Yes, it is.

Q: And that mesh lays under the urethra at the same place?

A: Yes.

Ex. C, Sirls 7/21/16 Dep. Tr. at 129:12–130:15.

By acknowledging the similarities and differences between the TVT-O/TVT-Abbrevo and TVT/TVT-Exact, Dr. Sirls factors this data in forming his opinions, just as he considers the products' characteristics in making his treatment decisions for real-world patients. *Id.* at 57:8–58:9 (citing the shorter length of the TVT-Abbrevo and the possibility of decreasing the already extremely infrequent symptom of groin pain as the reason for transitioning to the product from TVT-O), 61:1–7 (citing the curve of the trocar and hand movement as the reason he prefers the TVT-Exact, but noting that it is a personal preference).

B. Dr. Sirls' Opinions are Sufficiently Specific to the TVT and TVT-O Devices.

Leaving aside their argument about the TVT-Abbrevo device, it is unclear whether Plaintiffs are otherwise challenging Dr. Sirls' opinions as insufficiently "specific" to the TVT and TVT-O. In their Preliminary Statement, they assert that Dr. Sirls' "opinions based on data and clinical experience regarding devices other than the TVT or TVT-O are outside the scope of his opinion here." Pls.' Memo. at 2. However, they never follow up on this conclusory assertion elsewhere in their memorandum.

Nevertheless, Ethicon will address why Dr. Sirls' general opinions with respect to the TVT and TVT-O sufficiently "fit" the facts of this case and are reliable and admissible under *Daubert*. First, Plaintiffs do not and could not plausibly challenge Dr. Sirls' experience with these devices specifically. *See, e.g.*, Ex. C, Sirls 7/21/16 Dep. Tr. at 55:24–56:12; Ex. A, Sirls General Rep. at 29 (noting that Dr. Sirls has implanted thousands of mesh slings and other mesh

products). By Dr. Sirls' estimation, with respect to obturator slings, it is only within the last few years that he has transitioned from using the TVT-O to the TVT-Abbrevo, but he would still use the TVT-O if the TVT-Abbrevo was not available. Ex. C, Sirls 7/21/16 Dep. Tr. at 59:6–13. Dr. Sirls further notes that he still uses retropubic midurethral slings, including the TVT, in appropriate situations. *Id.* at 60:19–61:7; Ex. A, Sirls General Rep. at 3. Dr. Sirls also has extensive experience and training in other surgical treatments for stress urinary incontinence (SUI), including with other TVT products, and so is well-qualified to evaluate the comparative safety and efficacy of the TVT and TVT-O in his clinical practice and experience. Ex. A, Sirls General Rep. at 1–3.

What is more, Dr. Sirls' methodology for forming his opinions about the TVT and TVT-O devices included analyzing multiple, published, peer-reviewed studies relevant to each device specifically:

- **TVT.** Dr. Sirls cites Nilsson and Kuuva (2001), which found an overall objective cure rate of 87 percent at 16 months post-implantation. Ex. A, Sirls General Rep. at 30. He discusses and relies on Liapis (2008), which found a five-year objective cure rate of 83 percent and a seven-year objective cure rate of 80 percent. *Id*; *see also id.* at 31–34 (discussing TVT-specific studies including Ward and Hilton (2002, 2004, 2008), Rechberger (2009), Meschia (2006), and Lim (2005)).

- **TVT-O.** Dr. Sirls evaluated several long-term studies involving women who received the TVT-O implant. For example, he cited Cheng (2012), which followed 103 women with the TVT-O implant and, at five years post-implantation, found one vaginal mesh exposure and four patients with groin pain persisting to a year. *Id.* at 39. Dr. Sirls further analyzed Groutz, who published a 5-year efficacy study on TVT-O in 61 women, and Athanasiou, which followed up with 124 women receiving TVT-O implants seven years later. *Id.* at 40.

- **TVT vs. TVT-O Comparisons.** Dr. Sirls considered studies which involved both the TVT and TVT-O devices, including the TOMUS trial (Richter), which was a multicenter study funded by the National Institutes of Health that included a 24-month follow up (Albo) and a 5-year follow-up (Kenton). *Id.* at 35. Dr. Sirls also discusses and relies on Laurikainen, which involved both TVT and TVT-O patients and showed subjective success rates above 90 percent with objective cure rates greater than 80 percent for both groups. *Id.* at 40.

In short, Dr. Sirls thoroughly analyzed medical literature specific to the TVT and TVT-O devices, which in turn form the basis for his opinions in this case. Dr. Sirls' methodology is reliable and practiced by others in his field and his opinions concerning the TVT and TVT-O devices should be permitted. Ex. C, Sirls 7/21/16 Dep. Tr. at 133:8–14.

II. Dr. Sirls is Qualified to Offer the Opinions Stated in his Report and Deposition. (Pls.' Memo. Section B)

A. Dr. Sirls is Qualified to Offer Opinions, Based on his Experience, Training, and Extensive Review of the Medical Literature, Regarding Whether the IFUs Accompanying the TVT and TVT-O Reflect the Risks Associated with the Products that are Not Otherwise Common Knowledge.

Plaintiffs cite this Court's decision in *Sederholm v. Boston Scientific Corp.*, No. 2:13-cv-12510, 2016 WL 3282587, at *16 (S.D. W. Va. June 14, 2016), for the proposition that "medical experts are not qualified to offer opinions regarding the adequacy of a corporate defendant's IFU that accompanies a mesh device when marketed, based only on their own experience." Pls.' Memo. at 5. This argument fails as to Dr. Sirls for at least three reasons.

First, and most fundamentally, Dr. Sirls does not rely solely on his own experience with the TVT and TVT-O. *See* Ex. C, Sirls 7/21/16 Dep. Tr. at 28:23–29:5 (Dr. Sirls relied on clinical experience and medical literature, and discussions with colleagues, among other sources); *see also* Ex. A, Sirls General Rep. at 83. In particular, Dr. Sirls' extensive review of the medical literature concerning the risks and potential complications of surgical SUI treatment with the TVT or TVT-O helps inform his opinions with respect to the IFUs for these devices. *See* discussion *supra* Section I.B. Dr. Sirls' reliance on several different sources of information is sufficient to distinguish the circumstances here from *Sederholm*. *See Huskey*, 29 F. Supp. 3d at 734–35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature).

Second, "doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger v. Boston Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *15 (S.D. W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09–md–02100, 2011 WL 6301625, at *11 (S.D.Ill. Dec.16, 2011)). A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues). Likewise, a physician is qualified to testify about the adequacy of IFUs from a clinical perspective. *Id.* at *6–7, 15 (finding Dr. Galloway qualified to provide an opinion on IFUs based on clinical experience despite lack of familiarity with FDA rules or regulations for warnings). Accordingly, consistent with this Court's rulings in Wave 1, Dr. Sirls will opine regarding the relevant risks (or lack thereof), and whether or not those risks were contained in the IFU[3] or were otherwise within the common knowledge of pelvic floor surgeons during the relevant time period.[4] He will not be offered to opine on whether the IFU was legally "adequate."

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[3] *See, e.g., In re: Ethicon, Inc.*, 2016 WL 4536885, at *3 (holding that urogynecologists may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, but must possess additional expertise to offer testimony about what information should or should not be including in an IFU).

[4] Experts may testify as to the knowledge common within a profession or community. *See Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *United States v. Articles of Device*, 426 F.Supp. 366, 370 (W.D.Pa. 1977) (referencing two affidavits supplied by the FDA concerning the common knowledge of physicians with respect to acupuncture in a misbranding case); *Flannery v. Bauermeister*, No. CIV.A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community").

Third, the law imposes no duty to warn upon manufacturers for sophisticated users of products with respect to risks that they know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d §32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). This objective test is not dependent on the knowledge of the individual surgeon, and Dr. Sirls is competent to share his opinions about what risks would be obvious to surgeons, and how a reasonable pelvic floor surgeon would be expected to construe the TVT or TVT-O IFUs given their existing knowledge base. Given Plaintiffs' attack on the adequacy of Ethicon's warnings, it is only fair that Ethicon be allowed to defend itself by demonstrating that the risks they identify would have been obvious to the intended users of the device. Dr. Sirls has the training, experience, and knowledge of the peer-reviewed literature to enable him to reliably supply this testimony which Plaintiffs should challenge by cross-examination, not a motion to exclude.

In sum, Dr. Sirls' opinions regarding the IFUs accompanying the TVT and TVT-O are relevant and admissible.

B. Plaintiffs' Overbroad and Unsupported Request to Exclude Dr. Sirls' Opinions About "Regulatory Matters" Should be Denied.

In a two-sentence paragraph citing *Tyree*, Plaintiffs ask the Court to exclude Dr. Sirls' "opinions regarding regulatory matters." Pls.' Memo. at 5. Their challenge is overbroad, ill-founded, and misstates Dr. Sirls' opinions.

The only specific "opinion" Plaintiffs attack is a portion of Dr. Sirls' response to a question from Plaintiffs' counsel about whether adverse reactions listed in the post-2015 IFU could have been included in the pre-2015 IFU. Pls.' Memo. at 5. Dr. Sirls mentions FDA regulations in passing, but goes on to explain his main point: that the adverse reactions listed

already were commonly known to those practicing surgical treatment for SUI. Ex. C, Sirls 7/21/16 Dep. Tr. at 91:5–7. This is a far different scenario than that in *Tyree*, where the Court not only found that the expert had inappropriately relied upon federal statutes and regulations in forming her opinions, but had also not proffered any reason sufficient to pass muster under *Daubert* for her opinions on BSC's labeling practices. *See Tyree*, 54 F. Supp. 3d at 542–43 (concluding that the expert's opinion was based on *ipse dixit* sources like "the standard of care" and "a matter of ethics").

To the extent Plaintiffs are attempting to assert a broader challenge by reference to "regulatory matters" addressed in Dr. Sirls report, *see* Pls.' Memo. at 5, their characterization of that report is misleading and their objection should be denied. In his report, Dr. Sirls cited to several statements by the FDA with respect to the safety and efficacy of midurethral slings, including the FDA's findings on general safety and efficacy of such procedures and potential complications. Ex. A, Sirls General Rep. at 76–79, 84. But instead of offering opinions on the FDA's regulatory processes, as Plaintiffs suggest, Dr. Sirls uses these statements by the FDA to inform and support his opinions with respect to the TVT and TVT-O. *Id.* Indeed, this section of his report is titled "Position Statements" and describes how such statements from various medical associations and organizations, including the FDA, support Dr. Sirls' opinions here. *Id.* at 76–79. Plaintiffs' position is simply not supported by a review of Dr. Sirls' expert report and the Court should deny their request.

C. Dr. Sirls is Qualified to Offer Opinions Regarding How the TVT and TVT-O Interact Within the Body Based on His Extensive Clinical Experience and Review of the Medical Literature.

Plaintiffs question Dr. Sirls' expertise in "biomaterials" by pointing to various details regarding polypropylene mesh that Dr. Sirls was not able to supply at his deposition. Pls.'

Memo. at 6. Plaintiffs attack a straw man. Dr. Sirls explained (multiple times) in his deposition that he is a "***clinical expert in the use of these materials, their outcomes, [and] their complications***," not a "biomaterials" expert as Plaintiffs suggest. *See* Ex. C, Sirls 7/21/16 Dep. Tr. at 29:9–14, 31:1–3 (emphasis added). In other words, Dr. Sirls' opinions about the safety and efficacy of the TVT and TVT-O necessarily incorporate his clinical observations, and his knowledge gleaned from the medical literature, about the biocompatibility of the materials used in the TVT and TVT-O. Beyond that, Dr. Sirls does not purport to opine on the details of the chemical composition and properties of these materials. If Plaintiffs wish to do so, they may use cross-examination at trial to show Dr. Sirls purported lack of familiarity with different "grades" of polypropylene and other such details. Their challenge, however, does not render Dr. Sirls' opinions generally inadmissible.

In fact, this Court has previously found that clinicians experienced with mesh can provide sufficient qualification to offer opinions about "how the product reacts within the body" and it should do the same here. *Winebarger*, 2015 WL 1887222, at *26; *see also Tyree*, 54 F. Supp. 3d at 585 (finding urogynecologist who has performed almost 3,000 sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infection); *Huskey*, 29 F. Supp. 3d at 734 (finding Dr. Johnson qualified to opine as to mesh degradation); *Carlson v. Boston Sci. Corp.*, No. 2:13-CV-5475, 2015 WL 1931311, at *9–19 (S.D. W. Va. Apr. 28, 2015) (finding Dr. Galloway's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *In re: Ethicon, Inc.*, 2016 WL 4536885, at *3 (holding that Dr. Margolis, a urogynecologist, was qualified to testify regarding biomaterial properties including mesh reaction to and effect on the human body).

In sum, Dr. Sirls may not be qualified to offer advanced pathology opinions. *See* Pls.' Memo. at 6. But he does not purport to offer such opinions. Instead, Dr. Sirls' opinions are drawn from his own extensive clinical experience actually treating thousands of women with mesh slings like the TVT and TVT-O, as well as his thorough review of high-level scientific literature. The Court should deny Plaintiffs' motion on this ground.

III. Plaintiffs' Challenge Relating to Ethicon's Internal Documents is Insufficiently Specific, and Unsupported by the Record or the *Lewis* Decision. (Pls.' Memo. Section C)

Plaintiffs next assert that an expert may not properly offer opinions "grounded in the internal documents of a corporate defendant" about the company's knowledge, state of mind or conduct and ethics. Pls.' Memo. at 6–7. But Plaintiffs do not identify any such opinion by Dr. Sirls, nor do they point to any internal documents upon which he relied "inappropriately." This lack of specificity by itself justifies denying Plaintiffs' motion on this point. *See* discussion *supra* note 2; *see also Server Tech.*, 2014 WL 1308617, at *5–6; *Ratay*, 1993 WL 189864, at *1.

Regardless, a review of Dr. Sirls' general expert report demonstrates that he does not offer opinions regarding what Ethicon knew, its state of mind, or its corporate conduct. *See generally* Ex. A, Sirls General Rep. Rather, Dr. Sirls' opinion that "the mesh midurethral sling (MUS) procedure such as the TVT and TVT-O represent the most significant advances in the surgical management of female SUI" is based on his extensive clinical and medical experience, his participation in numerous studies involving the treatment of SUI, and his widespread review of the medical literature. *Id.* at 2–3.

And Dr. Sirls' deposition testimony about the Ethicon documents he reviewed belies any implication that he intends to offer corporate "state of mind" opinions—or that company documents informed his medical opinions. On the contrary, he testified that while he found

internal documents he reviewed "interesting" and reflective of "what was going on within the company," they did not inform his report or opinions stated therein: "My expert report is based on the literature." Ex. C, Sirls 7/21/16 Dep. Tr. at 14:23–15:11.

Plaintiffs' reliance upon *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872 (S.D. W. Va. Jan. 15, 2014), is misplaced. In *Lewis*, the plaintiffs' expert Dr. Uwe Klinge, unlike Dr. Sirls, did intend to opine specifically about Ethicon's alleged knowledge, state of mind, and corporate conduct, as well what Ethicon supposedly "should have" done. *See id.* at *5–6. By contrast, this Court has held that "an expert ***may*** testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions." *Huskey*, 29 F. Supp. 3d at 702–03 (emphasis added). Though internal documents did not inform Dr. Sirls' opinions about the safety and efficacy of the TVT and TVT-O devices, even if they had, *Lewis* does not provide grounds for the wholesale exclusion of expert opinions simply because they were informed in part by a review of corporate documents.

Accordingly, Plaintiffs' motion to exclude Dr. Sirls' general opinions on this basis should be denied.

IV. Plaintiffs' Cursory Request that the Court "Limit" Dr. Sirls' Trial Testimony in Accordance with his Deposition Testimony Does Not State a Proper *Daubert* Challenge and Should be Denied. (Pls.' Memo. Section D)

Finally, Plaintiffs append a bullet-point list containing their characterizations of snippets of Dr. Sirls' testimony, followed by a one-sentence "argument:" "His opinions must now be limited to the parameters of the above testimony." Pls.' Memo. at 7. Apparently, Plaintiffs are asking the Court to predetermine what trial testimony Dr. Sirls might offer that would fall outside these putative "parameters," and issue what amounts to an advisory opinion that such testimony will be inadmissible.

Leaving aside the accuracy or relevance of their characterizations of Dr. Sirls' opinions, Plaintiffs fail to state a proper *Daubert* objection. *See* Fed. R. Civ. P. 7(b)(1)(B) (motion must state with particularity the relief sought); *cf. Karaginnopoulos v. City of Lowell*, No. 3:05-CV-401-FDW-DCK, 2008 WL 2090726, at *1 (W.D.N.C. May 14, 2008) (denying motion to compel in part because movant cited no authority and failed to articulate a persuasive rationale for relief sought). Rather, Plaintiffs appear to be previewing their strategy for cross-examining Dr. Sirls at trial based on what they believe to be concessions made at his deposition—for example, that the TVT and TVT-O devices "can both rope, curl, and otherwise change shape," and that he has treated women with "mesh exposure or erosion." Pls.' Memo. at 7. But while a discrepancy between an expert's trial and deposition testimony may be fertile ground for impeachment, it is not a proper basis for a preemptive *Daubert* challenge before the trial testimony has even occurred. Plaintiffs have not identified any specific testimony by Dr. Sirls they seek to exclude, much less how it fails to comport with Federal Rule of Evidence 702 or *Daubert*.

If Dr. Sirls testifies at trial in a manner that Plaintiffs believe contradicts his deposition testimony, they are free to cross-examine him on that point. The Court should deny their premature and speculative request to "limit" his testimony.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that the Court deny Plaintiffs' motion to exclude or limit the testimony of Dr. Sirls.

Respectfully Submitted,

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Dated: October 11, 2016

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CERTIFICATE OF SERVICE

I certify that on October 11, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

s/ Christy D. Jones